

Medical Products

TD

Safety Information

System

General Safety Notes

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Important Remarks

Introduction

The following general safety notes are supplemented by specific descriptions in the documents supplied by us, e.g. product documents, ARTD (general guidelines) as well as by written instructions in specific cases.

All safety instructions must be observed in the performance of work and tests; in addition, there must be compliance with prescribed country-specific requirements (e.g. occupational safety and accident prevention regulations).

NOTE

The particular applicable ARTDs (General Guidelines for Technical Service) can be found on the Intranet on the following path: http://www-td.med.siemens.de/rootcollection/Med_TD/Management/Quality_Management/TDQ_WORK/guidelines-artd-gesamt.htm

Changes made in products shipped by us

Changes made in products/systems shipped by us must not be implemented without our written release; this applies in particular to changes which may affect the mechanical and/or electrical safety or radiation-protection properties of a product (e.g. changing of safety distances, removal of locks/instructions, enlargement of the radiation exit window on the lead cone, etc.).

Safety Notes and Symbols

The use of signal words and their levels anticipate the new Medical Solutions CS Standard (CS = Customer Services, previously Technical Service), which is based on the ANSI Z535.4 Standard.

Safety Notes

Emphasized texts in technical documentation have the following meaning:




 DANGER	DANGER indicates when there is an immediate danger that l e a d s to death or serious physical injury.
 WARNING	WARNING indicates a risk of danger that m a y l e a d to death or serious physical injury.
 CAUTION	CAUTION used with the safety alert symbol indicates a risk of danger that leads to slight or moderate physical injury and/ or damage to property.
NOTICE	NOTICE used without the safety alert symbol indicates a risk of danger that if disregarded leads or may lead to a potential situation which may result in an undesirable result or state other than death, physical injury or property damage.

Fig. 1: Safety Notes

Changes Regarding Notice and Note

Up to this time, both the warning as well as the obligatory notes have been introduced in German language documentation with “Hinweis”. In the future, a distinction will be made between these two types of information.

Notice / Achtung











In the future, the word “Notice” (in German “Achtung”) will have a warning character.

Note / Hinweis

The note “Note” should be understood as a **tip**. The user does not absolutely have to observe these instructions. However, there will be advantages if he does.

The American term “Note” should continue to be translated as “Hinweis”. Consequently, the term “**Hinweis**” should also only be used when reference to a possible **advantage** is made.

Appearance on Paper and Online

Paper (black/white)	online = html-file (color)
 <i>Fig. 2:</i>	 (white type on a red background)
	 (black type on an orange background)
	 (black type on a yellow background)
	 (black type on a blue background)
	 (black type on a green background)

Symbols

The symbols appear in black/white in paper documents and in color online.

Notes in technical documentation that are labeled with the following symbols have the meanings explained below:



For X-radiation

X-ray

Warning for ionizing radiation;
radioactive material ([Radiation Safety / p. 9](#)).



For Caution

Caution

In older documentation, this symbol was also used as a note for a torque value.
Warning for a general dangerous situation.



For Torque Value

Torque

Note about a threaded connector with a torque value ([Screw connections / p. 10](#)).



For Entry of Measurement Result

Certificate

Note for entry in certificates.



For Lasers

Laser

Warning for a laser beam ([Laser radiation / p. 10](#)).



For Voltage

Voltage

Dangerous electrical voltage > 25 V~ or > 60 V- ([Work in connection with voltage / p. 9](#)).



For Magnetic Field

Magnetic Field

Warning for a magnetic field



For Electrostatically-sensitive Component

ESD

Warning for electrostatically-sensitive components ([Protection of electrostatically-sensitive devices / p. 10](#)).

Please Note:

Room Installations

Electrical installations of medically used rooms in the Federal Republic of Germany must be made in accordance with the requirements of VDE Regulations 0107.

For all other countries, the regulations to be complied with (national and VDE regulations) must be taken from the installation sheets for the project concerned.

Ground Wire Connections

All work must be carried out in accordance with the technical documentation.

Make sure that all **protective ground wires** provided by the manufacturer are connected properly before starting the equipment after installation. This applies, for example, to all metallic covers which may develop a dangerous contact voltage if there is a malfunction. They must always be connected to the protective ground wire. To ensure this, the connection between these covers and the protective ground wire must be made with screws and contact washers or by means of the protective ground wires provided.



; means **connection points for equipment ground wires**.

The protective ground wires must be connected between the system components and the power supply as shown in the wiring diagram.

In the interest of the safety of our personnel and others, the protective ground wires must be installed prior to first switching on the product/system, as well as after completing all work, before turnover to the customer, in accordance with the product documentation.

Personal protection measures (occupational safety)

The legally relevant and internal regulations and specifications concerning occupational safety and accident prevention must be observed, primarily in the interest of the persons performing the work.

The notes below are given as additional information.

Unpacking

- When unpacking, look for shipping damage that could later have an adverse effect on function and safety.
- Use only proper tools to avoid the risk of accident and damage to the contents.
- Each crate is secured with metal strapping. There is **serious risk** of accident, particularly **for eyes**, when cutting the straps. The cut ends can lash back unexpectedly.
- Pull only nails out of the crate boards that have a cardboard or metal disk under the heads.

Pull nails out completely and dispose of them properly. Wear sturdy shoes.

- Always observe the directional markings on the crates during transport, storage and unpacking.

Transport safety devices

All parts painted **red** on the unit as well as on the assemblies are transport safety devices that may be removed only in accordance with the instructions in the technical documentation.

Replacement of damaged or missing Installation Hardware

Damaged or missing installation hardware (such as steel cables, washers, etc.) may be replaced only with original parts.

Work in connection with voltage

Working on parts that are under voltages of $> 25\text{ V} \sim$ or $> 60\text{ V-}$ may not be performed (see guideline ARTD-002.731.17.02.02). Power must be switched off to the system using the EMERGENCY OF switch.

This prohibition does not apply for measuring and adjustment procedures. Be careful when performing these procedures. Use only tools and measuring instruments which are suitable for the respective procedure.

Test and adjustment points must be accessible without any risk of injury for personnel. If this is not possible, switch off the system.

If voltage must be applied during an operation, e.g. to perform unit movements, please pay particular attention to any danger due to moving and rotating parts. Deenergize the unit immediately afterwards.



Risk of injury!

For activities in the product danger zones, there is significant risk of injury that can be caused by unintentional unit movements.

⇒ **Press the service or EMERGENCY STOP switch.**

Body protectors

If there is any risk of injury, body protectors must be used. It is essential to observe the notes given in the documentation.

Radiation Safety

Ionizing radiation can lead to radiation injuries if handled incorrectly. When radiation is applied, the required protective measures must be complied with in any event.

Mandatory reporting

The supervisor in charge must be notified at once in the event of an accident or if there are any hazards which may cause an accident.

For this, please observe the corresponding instructions.

Screw connections

Tightening torques for screw connections

All existing screw connections must be tightened sufficiently firmly, but they may not be overstressed when tightening.

There must always be compliance with stated torque values!

NOTE

All screws must be secured in accordance with the corresponding data.

If "Loctite" has to be used to secure screws, this is stated in the text.

Replacement of damaged or missing screws

Damaged or missing screws may be replaced only with the same screw types that have the specified hardness rating.

Unless a different value is listed in the instructions, all Allen screws used must be hardness rated 8.8.

Protection of electrostatically-sensitive devices

The used integrated circuits and PC boards, which are equipped with electronic modules, require especially careful handling because of their electrostatically very sensitive structures and their extremely high input impedances.

Use the prescribed means of protection.

Laser radiation

According to its classification, laser radiation can lead to eye and skin injuries (Class 1 to 4); in addition, an extract from guideline ARTD-002.731.03.01.02, use must be in accordance with regulations:

- **Class 1:** not dangerous to the human eye.
- **Class 2:** Laser units having a maximum output of 1 mW. The accessible laser radiation only lies within the visible range of the spectrum (400 nm to 700 nm). With brief exposure times (up to 0.25 s) there is no danger due to the blink reflex.

⚠ WARNING

Class 3A: Laser units having a maximum output of 5 mW. The accessible laser radiation becomes dangerous for the eye, if the cross section of radiation is reduced by optical instruments. If this is not the case, the emitted laser radiation in the visible region of the spectrum, with short exposure times (up to 0.25 s), is not dangerous in the spectral regions, even for long irradiation times.

- ⇒ Proper use must be observed.
- ⇒ Required safety equipment must be used.

⚠ WARNING

Class 3B: Laser units having a maximum output of 500 mW. Dangerous to the human eye and in particular cases to the skin.

- ⇒ Proper use must be observed.
- ⇒ Required safety equipment must be used.

⚠ WARNING

Class 4: Laser units having a higher output than 500 mW. Extremely dangerous to the human eye and dangerous to the human skin.

- ⇒ Proper use must be observed.
- ⇒ Required safety equipment must be used.

NOTE

Note the detailed instructions in the technical documentation!

Batteries

For replacement of batteries, special preventive measures apply.

In the case of lithium batteries, there is as risk of explosion if they are incorrectly installed.

The notes concerning handling and disposal must be observed in each case.

Handling Heavy Loads

Apart from wearing the required protective clothing, e.g. safety boots and gloves, care must be taken that heavy loads are correctly lifted/carried to avoid injury to health (e.g. injuring the spine).

The relevant instructions must be complied with.

Heavy or awkward loads must be moved by mechanical means or by several persons.

Handling Hazardous Materials

Hazardous materials is the designation for substances which can ignite or explode or which are toxic, injurious to health, corrosive or irritating.

Their properties together with the hazards and protective measures connected with them are identified clearly by symbols and described by the instructions appertaining to the hazardous substances.

Before they are handled, these instructions must be read and the required protective measures must be complied with when performing work to avoid health risks.

In addition, there must be compliance with all relevant instructions in the documentation.

- **Important Remarks:** an additional note added.
- **Working in Conjunction with Electrical Voltage:** per ARTD-002.731.17.02.0w, Pt. 4.2, the new voltage values have been inserted (> 25 V ~ and > 60 V-).
- CR No.: 020815 TDSD

